Our Ref. No.: 003764.P002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Pinaki Ray	Examiner: **Williams, Catherine Serke**
Application No.: **09/475,768**	Art Unit: **3763**
Filed: **December 30, 1999**	Confirmation No.: **6849**
For: **CONDUIT SYSTEM FOR ISOLATION OF FLUIDS IN BIOLOGICAL TISSUES**	

APPEAL BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant submits the following Appeal Brief pursuant to 37 C.F.R. §41.37(c) for consideration by the Board of Patent Appeals and Interferences. Applicant also submits herewith a check in the amount of $500.00 to cover the cost of filing the opening brief as required by 37 C.F.R. §1.17(f). Please charge any additional amount due or credit any overpayment to Deposit Account No. 02-2666.

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I. REAL PARTY IN INTEREST

Pinaki Ray, the party named in the caption, transferred his rights to the subject Application through an assignment recorded on March 2, 2000 (Reel/Frame 010682/0449) in the patent application to Advanced Cardiovascular Systems, Inc., of Santa Clara, California. Thus, as the owner at the time the brief is being filed, Advanced Cardiovascular Systems, Inc. is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will affect or be affected by the outcome of this appeal.

III. STATUS OF CLAIMS

Claims 1-13 and 48-64 are pending and rejected in the Application. Applicant hereby appeals the rejection of all pending claims.

IV. STATUS OF AMENDMENTS

The claims are amended in accordance with an Amendment and Response to Office Action filed August 18, 2004. The claim amendment presented at that time were entered. Applicant inadvertently titled a response filed March 31, 2005 as an Amendment and Response to Final Office Action. However, no amendments were presented at that time. Accordingly, the claims stand as amended March 18, 2004.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The pending claims relate to a fluid isolation system, in one embodiment, for confining fluid to a target tissue. The claims utilized upstream and downstream conduits that are positioned to allow the fluid to flow along a tissue's circulatory pathway. An upstream channel, e.g., vessel, sinus or artery, is a passageway for an incoming fluid stream to a biological mass typically supplies nutrients to the mass. See Application, page 16, lines 1-4. Thus, where the fluid contains an agent, the upstream channel usually directs the agent into the biological mass (target tissue) for deposition in the biological mass. See Application, page 16, lines 4-6. Likewise, a downstream channel, e.g., vessel, sinus or vein, usually directs the stream flowing out of the same mass (target tissue) and they remove waste and excess nutrients from the mass (target tissue). See Application, page 16, lines 6-7. The upstream and downstream channels are fluid communication with each other. See Application, page 16, lines 10-11. The details of one exemplary catheter system are illustrated in

Figures 3A and 3B. Figure 3A shows an elongated catheter shaft 56 having a terminal end 68 and control end 58. Control end 58 has a pressure attachment 62, i.e., port for inflating the seal, guide wire port 60 and fluid source opening 64. A balloon is positioned proximal to terminal end 68 of the catheter and is adapted to expand and engage an external wall with a fluid tight seal. In this manner, injected fluid is prevented from escaping through the channel in which balloon 54 is located and flowing away from a target tissue. One or more delivery openings 70 may be located on balloon 54 for ejecting fluid into the walls of the channel. Catheter 52 may be placed through a typical percutaneous transluminal coronary artery (PTCA) guide wire 72 to access a site for therapy.

The details of one embodiment of a collection catheter are illustrated in Figures 4A and 4B. Collection catheter 82, as shown in Figure 4A, is similar to the delivery catheter described above with reference to Figures 3A and 3B in terms of dimensions and material. Collection catheter 82 includes shaft 86 with control end 88 and terminal end 98. Analogous to delivery catheter 52, collection catheter 82 has both drainage opening 94 and optional pressure attachment 92 at control end 88 as well as guide wire port 90 at or proximal to control end 88. As with delivery catheter 52, seal 84, e.g., balloon, is positioned proximal to terminal end 98 and optionally guide wire protrusion 102. Terminal end 98 of collection catheter 82 includes one or multiple collection ports 100 dispersed throughout seal 84 for receiving fluid as well as other components flowing in the fluid stream, such as floating plaque.

Referring to Figure 4B, drainage lumen 108 is in fluid communication with drainage opening 94 at control end 88 and collection ports 100 at terminal end 98. In representative embodiments, a drainage pressure is applied to the opening through the drainage lumen. Guide wire lumen 104 communicates with guide wire port 90 and seal (balloon) inflation lumen 106 is in fluid communication with the interior of seal 84? (balloon) at the terminal end and pressure attachment 92 at the control end, for providing pressure to the balloon.

VI. <u>GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL</u>

The grounds of rejection involved in this appeal are:

Whether claims 1-13 and 48-60 are obvious under 35 U.S.C. §103(a) over U.S. Patent No. 4,192,320 issued to Boddie (<u>Boddie</u>) in view of U.S. Patent No. 4,540,402 issued to Aigner (<u>Aigner</u>); and

Whether claims 61-64 are obvious under 35 U.S.C. §103(a) over <u>Boddie</u> in view of <u>Aigner</u> and further in view of U.S. Patent No. 5,452,733 issued to Sterman et al. (<u>Sterman</u>).

VII. ARGUMENT

A. Overview of the Cited References

1. Overview of Boddie Reference

Boddie describes the technique for isolating a liver to allow chemotherapy treatment. The technique provides a plurality of shunt that allows blood circulation from the lower part of a patient's body and from the intestines to flow unimpeded to the heart, while isolating hepatic venous blood containing toxic agents from the general circulation and returning the hepatic venous blood to a heart lung machine. As a result, the assembly can be used to perfuse the liver of a patient with high doses of cancericidal chemotherapy agents, while at the same time avoiding toxic effects of these agents on the patient's body as a whole. See Boddie Abstract.

Boddie describes hepatic isolation and perfusion circuit assembly 10, including a source of a plurality of cancericidal chemotherapy agents for perfusing a cancer-involved liver; heart-lung machine 30 connected to the source of cancericidal chemotherapy agents 20; inlet 33, outlet 34, that is bifurcated into first branch catheter 35 and second branch catheter 36; and a source of oxygen. See col. 2, lines 13-26. With reference to figure 3, first branch catheter 35 "is removably inserted into, is conformally engaged with, and is releasably secured to the hepatic artery" and second branch catheter 36 is removably inserted into, is conformally engaged with, and is releasably secured to a pre-selected location L1 at end in the portal vein." Col. 2, line 26-32. Isolation and perfusion circuit assembly 10 also includes means 40 for selectively isolating a patient's liver and the blood circulating therein from the general circulatory system of the patient, with means 40 releasably connected to heart-lung machine 30. See col. 2, lines 32-37. Means 40 is described in enbodiment as a subassembly including first catheter 41, having inlet 42, outlet 43, first opening 44, second opening 45, and third 46. See col. 2, lines 38-41 and figures 2-3. Outlet 43 is "removably inserted into, conformally engaged with, and releasably secured to the inferior vena cava" at location L2 between the liver and the kidneys. See col. 2, lines 41-44. Outlet 43 is simultaneously positioned and in communication with a far right atrium of the patient's heart. Col. 2, lines 44-46. Inlet 42 protrudes from the inferior vena cava. Col. 2, lines 47-48. In addition to first catheter 41, the sub-assembly includes second catheter 50, having inlet 51 and outlet 52, with inlet 51 "removably inserted into, conformally engaged with, and releasably secured to" the inferior vena cava at location L2. See col. 2, lines 48-52. A loop is formed external of the inferior vena cava with outlet 52 of second catheter 50 directionally oppositely exposed with relation to outlet 43 of first catheter 41 and with outlet 52 of second catheter 50 protruding from the inferior vena cava and releasably connected to inlet 42 of first catheter 41. Hepatic venous return line 60 including a tube 61 having inlet 62, outlet 63 and portion 64 between inlet 62 and outlet 63 passes

into first catheter 41 through second opening 45 and, inlet 62 of tube 61, positioned internally of first catheter 41 and in sealing communication with first opening 44 of first catheter 41. See col. 2, lines 57-65. Intermediate portion 64 to 61 is positioned and conformally engaged with second opening 45 and first catheter 41, and further, with outlet 63 of tube 61, positioned externally of first catheter 41 and releasably connected to inlet 33 of heart-lung machine 30. See col. 2, line 65 through col. 3, line 3. Portal shunt sidearm 70 passes through and conformally engages with third opening 46 of first catheter 41. Shunt sidearm 70 includes outlet 71, positioned internally at first catheter 41 and inlet 72, positioned externally at first catheter 41. See col. 3, lines 3-8. The sub-assembly described as a portion of means 40 also includes third catheter 80, having inlet 81 and outlet 82. See col. 3, lines 8-9. Outlet 82 is releasably connected to inlet 71 of portal shunt sidearm 70 with inlet 81 with "removably inserted into, conformally engaged with, and releasably secured" to the portal vein at location L1. Col. 3, lines 11-15. Third catheter 80 is directionally oppositely disposed with relation to second branch catheter 36. See col. 3, lines 16-17. Blood flow is occluded by means 90 (ligature) disposed upstream of the location of first branch catheter 35 in the hepatic artery to occlude blood flow from flowing into liver from the hepatic artery. See col. 3, lines 17-21.

Boddie does not say specifically how its assembly or system is installed in the body. However, there are clues that indicate installation by way of an open chest cavity procedure. For example, Boddie describes securing catheters to vessels. See col. 2, lines 25-28 (first branch catheter 35); col. 2, lines 29-32 (second branch catheter 36). Boddie also describes ligatures used to hold catheters. See col. 3, lines 29-38. Boddie also preferably chooses a ligature to occlude blood flow into the liver from the hepatic artery. See col. 3, lines 40-42. No other blood flow occlusion is described.

Boddie teaches that, as a matter of preference, ligatures are used to conformally engage and releasably hold first branch catheter 35 to the hepatic artery, second branch catheter 36 to the portal vein, outlet 43 of first catheter 41 to the inferior vena cava, outlet 43 of first catheter 41 to the right atrium, inlet 51 as second catheter 50 to the inferior vena cava, and inlet 81 of third catheter 80 to the portal vein. See col. 3, lines 28-39. Means 90 for occluding blood flowing into the liver from the hepatic artery also preferably as a ligature. See col. 3, lines 40-42.

2. Overview of Aigner Reference

Aigner describes a profusion catheter of a splint catheter of a smaller catheter for isolating the liver without disrupting circulation through the vena cava and vena portae permitting withdrawal of blood from the liver. Similar to Boddie, Aigner does not specifically say how the

catheter is installed in a body. However, there are clues that indicate installations by way of open chest cavity. First, the splint catheter has a length of 250 millimeters (about 10 inches). See col. 2, line 12. Second, the entire length of the splint catheter fits in the vena cava. See col. 4, lines 42-43. Aigner teaches ligating the vessels from the outside. See col. 4, lines 43-45. Alternatively, a balloon may be used on the catheter matches from the outside. See col. 4, lines 49-52.

3. Overview of Sterman Reference

Sterman describes a method for closed-chest cardiac surgical intervention including viewing a region of the heart through a percutaneously positioned viewing scope such as a thoracoscope. See col. 2, lines 15-18. In one embodiment, a patient's arterial system is partitioned by endovascularly advancing a distal end of a catheter to a desired location within the ascending aorta and expanding a blocking element on the catheter to inhibit flow of blood and other fluids past the location. See col. 2, lines 18-26. Such partitioning isolates the heart and permits the heart to be stopped while the patient is supported by cardiopulmonary bypass. See col. 2, lines 26-28. Once a patient's heart is stopped, a variety of surgical procedures can be performed using percutaneously instruments in a minimally invasive fashion. See col. 2, lines 28-32.

B. Rejection of Claims 1-9, 12-13 & 48-60 As Obvious Over Boddie in View of Aigner

The patent office rejected claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103(a) as obvious over Boddie in view of Aigner. In making a rejection under 35 U.S.C. §103(a), the patent office bears the initial burden of presenting a *prima facie* case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). A *prima facie* case of obviousness is established when we're teaching from the prior art itself or appear to have suggested the claimed subject matter to the person of ordinary skill in the art. See id.

Independent claim 1 describes a system including a delivery conduit and a collection conduit. The delivery conduit has a length dimension suitable to be positioned from a first externally accessible channel of a patient adjacent to or into at least one upstream channel of a biological mass by way of a percutaneous transluminal route. The collection conduit has a length dimension suitable to be positioned from a second externally accessible channel of a patient adjacent to or into at least one downstream channel of the biological mass by way of percutaneous transluminal route.

Claim 1 provides specific structural limitations to the delivery conduit and the collection conduit. The length dimension of each is defined in terms of externally accessible channels of a patient. The second structural limitation of each of the delivery conduit and the

collection conduit is that they each have a dimension, e.g., diameter, that allows each conduit to be positioned within the patient by way of a percutaneous transluminal route. The collection conduit includes a collection seal having a dimension, in one configuration, to occlude a channel (a downstream channel).

Claim 1 is not obvious over the cited references, because the references do not describe a delivery conduit and a collection conduit, each having a length dimension as noted in a dimension suitable to be positioned by way of a percutaneous transluminal route. It may be that placing a catheter within a blood vessel during an open chest cavity procedure constitutes "percutaneous transluminal," at least where the blood vessel is opened and the catheter is inserted. However, such a procedure does not account for the length dimension as positioned from an externally accessible channel of a patient to a desirable position by way of a percutaneous transluminal route. Further, an opened-chest cavity procedure to access a blood vessel does not make the blood vessel externally accessible.

Claim 1 is further not obvious over the cited references, because there is no motivation to combine the teachings of Aigner with Boddie to obtain the system of claim 1. Boddie teaches introducing chemotherapy agents 20 through first branch catheter 35 inserted into and conformally engaged with the hepatic artery. See Boddie, col. 2, lines 23-28. Upstream of the entry point of first branch catheter into the hepatic artery, the hepatic artery is occluded (to prevent blood flow into the liver) . See Boddie, figure 3. The occlusion is preferably done by a ligature. See col. 3, lines 40-42. To substitute a balloon for the ligature preferred by Boddie, one presumably would have to branch first branch catheter 35 in a direction downstream (toward the liver) and a position upstream. The upstream-directed branch would contain the balloon catheter portion. Such a branch device is far beyond the teachings of Aigner or Boddie. It is also not clear if a ligature would not still be necessary to stop blood flow while the branch device was placed. In such case, a ligature is necessary; there is no reason for a balloon.

The other ligatures described in Boddie appear to teach conformally engaging and releasably holding catheters to arteries or veins, not to block them. Accordingly, substituting a balloon for any of these ligatures would not be suitable.

For the above-stated reasons, claim 1 is not obvious over the cited references. Claims 2-9 and 12-13 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-9 are not obvious over the cited references.

Independent claim 48 describes a system including a delivery conduit, a collection conduit, and a fluid to be administered to a biological mass through the delivery conduit and collected by the collection conduit. The delivery conduit has a length dimension suitable to be positioned by a percutaneous transluminal route from a first externally accessible channel of a patient. The collection conduit also has a dimension suitable to be positioned by percutaneous transluminal route from a second externally accessible channel of a patient.

Claim 48 is not obvious over the cited references, because the cited references do not describe a delivery conduit or a collection conduit having a length dimension suitable to be positioned by percutaneous transluminal route from an externally accessible channel of a patient. As noted above, with respect to claim 1, Boddie and Aigner both appear to describe open chest cavity procedures to access blood vessels of a patient, i.e., not by way of externally accessible channels. Further, since Boddie and Aigner proceed by an apparent open chest cavity procedure, there is no requirement that the catheters in those references have a dimension suitable to be positioned by percutaneous transluminal route from an externally accessible channel.

Claim 48 is further not obvious over the cited references because there is no motivation to combine the teachings of Aigner and Boddie to obtain the system of claim 48. As noted above with respect to claim 1, it does not appear practical or even feasible to achieve the occluding of the hepatic artery by adding a balloon to first branch catheter 35 of Boddie to replace the preferred ligature. Further, none of the other ligatures described by Boddie are used as occlusive devices.

Claims 49-60 depend from claim 48 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 48, claims 49-60 are not obvious over the cited references.

Applicant respectfully requests the Patent Office withdraw the rejection to claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103(a).

C. Rejection of Claims 10-11 As Obvious Over Boddie in View of Aigner

The patent office rejects claims 10-11 under 35 U.S.C. §103(a) as obvious over Boddie in view of Aigner. The rejection is similar to the rejection of claim 1 with the patent office adding that it would obvious to isolate the human heart based on the teachings of Boddie rather than the liver with a bypass where a delivery conduit would be positioned into the aorta and a collection conduit positioned into the coronary sinus.

Claims 10-11 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 10-11 are not obvious. In addition, Boddie and Aigner deal with isolating the liver. Neither reference provides a teaching or motivation for isolating a portion of the human heart. Applicant respectfully requests that the patent office withdraw the rejection to claims 10-11 under 35 U.S.C. §103(a).

D. Rejection of Claims 61-64 As Obvious Over Boddie in View of Aigner and Obvious Over Sterman

The Patent Office rejects claims 61-64 over Boddie in view of Aigner in further in view of U.S. Patent No. 5,452,733 of Sterman et al. (Sterman). Boddie and Aigner are cited for their teachings noted with respect to the other claims. Sterman is cited for teaching a method of accessing a heart with a catheter via a jugular vein (i.e., a percutaneous transluminal route). In other words, the Patent Office believes it would be obvious to modify the open chest cavity technique of Boddie and Aigner with a closed cavity (percutaneous transluminal) technique of Sterman.

Claims 61-62 depend from claim 1 and claims 63-64 depend from claim 48. For at least the reason stated with respect to claims 1 and 48, claims 61-64 are not obvious over the cited references. Further, there is absolutely no suggestion in Sterman that its closed chest cavity procedure for performing, for example, coronary bypass grafts, may be utilized in the liver treatment technique described in Boddie.

For the above stated reasons, Applicant respectfully requests that the Patent Office withdraw the rejection to claims 61-64 over the cited references.

VIII. CONCLUSION AND RELIEF

Based on the foregoing, Applicants request that the Board overturn the rejection of all pending claims and hold that all of the claims of the present application are allowable.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Nedy Calderon 8/19/05

Nedy Calderon Date

IX. APPENDIX

The claims involved in this Appeal are as follows:

1. (Previously Presented) A system for fluid isolation in a biological mass having at least one upstream channel and at least one downstream channel, comprising:

a delivery conduit for administering a fluid to the biological mass, the delivery conduit having a length dimension suitable to be positioned from a first externally accessible channel of a patient adjacent to or into at least one upstream channel of the biological mass by way of a percutaneous transluminal route; and

a collection conduit for acquiring the administered fluid, the collection conduit having a length dimension suitable to be positioned from a second externally accessible channel of a patient adjacent to or into at least one downstream channel of the biological mass by way of a percutaneous transluminal route and having a collection seal having a dimension, in one configuration, to occlude the at least one downstream channel;

wherein the biological mass is selected from the group consisting of a heart, a portion of a heart, a kidney, a portion of a kidney, a stomach, a liver, and a brain.

2. (Original) The system of claim 1, further including a driving force in communication with the delivery conduit for encouraging fluid through the delivery conduit.

3. (Original) The system of claim 1, wherein the delivery conduit is for administering fluid during at least a substantial period of diastole.

4. (Original) The system of claim 1, wherein the delivery conduit is for administering fluid during the period of diastole and the period of systole.

5. (Previously Presented) The system of claim 1 wherein the delivery conduit further includes a delivery seal having a dimension, in one configuration, to occlude the at least one upstream channel and the delivery conduit defines a delivery opening distal to the delivery seal.

6. (Original) The system of claim 5 wherein the delivery seal is an elastomeric balloon.

7. (Currently Amended) The system of claim 6, wherein, in another configuration, the delivery seal allows fluid flow past the delivery seal.

8. (Original) The system of claim 7, further including a seal control mechanism for contracting and expanding the delivery seal.

9. (Original) The system of claim 8, wherein the seal control mechanism is configured to expand the delivery seal during at least a substantial period of diastole and contract the delivery seal during at least a substantial period of systole.

10. (Original) The system of claim 1, wherein the biological mass is a human heart.

11. (Currently Amended) The system of claim 1, wherein the delivery conduit is such that the delivery conduit may be positioned into an aorta of a patient and the length dimension of the collection conduit is such that the collection conduit may be positioned into a coronary sinus of the patient.

12. (Original) The system of claim 1, wherein the fluid includes an agent.

13. (Original) The system of claim 12, wherein the agent is selected from the group consisting of natural and synthetic drugs, growth factors, gene therapy compositions, chemotherapeutic chemicals, anti-bacterial chemicals, anti-angiogenic chemicals and any combination thereof.

14-47. (Canceled)

48. (Currently Amended) A system comprising:

a delivery conduit having a length dimension suitable to be positioned by a percutaneous transluminal route from a first externally accessible channel of a patient adjacent to or into an upstream channel of a biological mass selected from the group consisting of a heart, a portion of a heart, a kidney, a portion of a kidney, a stomach, a liver, and a brain, and where the biological mass comprises at least one upstream channel and at least one downstream channel;

a separate collection conduit having a dimension suitable to be positioned by a percutaneous transluminal route from a second externally accessible channel of a patient adjacent to or into a downstream channel of the biological mass, the separate collection conduit comprising a collection seal for occluding fluid flow by the collection seal; and

a fluid to be administered to the biological mass through the delivery conduit, and reclaimed by the collection conduit, wherein the system achieves fluid isolation in the biological mass between the upstream channel and the downstream channel has at least one upstream channel and at least one downstream channel.

49. (Previously Presented) The system of claim 48, wherein the fluid further comprises an agent.

50. (Previously Presented) The system of claim 49, wherein the agent is selected from the group consisting of natural and synthetic drugs, growth factors, gene therapy compositions, chemotherapeutic chemicals, anti-bacterial chemicals, anti-angiogenic chemicals, and combinations thereof.

51. (Previously Presented) The system of claim 48, wherein the delivery conduit further comprises a delivery seal for occluding external fluid flow.

52. (Previously Presented) The system of claim 51, wherein the delivery seal comprises an elastomeric balloon.

53. (Previously Presented) The system of claim 48, further comprising a pressure device, wherein the pressure device is in fluid communication with the delivery conduit.

54. (Previously Presented) The system of claim 53, wherein the pressure device exerts a positive pressure, and the pressure device is selected from the group consisting of positive displacement pumps, syringes, vacuum pumps, delivery pumps, suction pumps, metering pumps, and intra-aortic balloon pumps.

55. (Previously Presented) The system of claim 48, further comprising a pressure device in fluid communication with the collection conduit.

56. (Previously Presented) The system of claim 55, wherein the pressure device exerts a negative pressure, and the pressure device is selected from the group consisting of positive displacement pumps, syringes, vacuum pumps, delivery pumps, suction pumps, metering pumps, and intra-aortic balloon pumps.

57. (Previously Presented) The system of claim 48, wherein the delivery conduit comprises a delivery catheter, wherein the delivery catheter includes three internal lumens.

58. (Previously Presented) The system of claim 48, wherein the delivery conduit comprises a delivery catheter, wherein the delivery catheter comprises as separate lumens, a balloon inflation lumen, a guidewire lumen, and a drug delivery lumen.

59. (Previously Presented) The system of claim 48, wherein the separate collection conduit comprises a collection catheter, wherein the collection catheter comprises three lumens.

60. (Previously Presented) The system of claim 48, wherein the separate collection conduit comprises a collection catheter, wherein the collection catheter comprises as separate lumens, a drainage lumen, a guidewire lumen, and a balloon inflation lumen.

61. (Previously Presented) The system of claim 1, wherein the first externally accessible channel is selected from one of a femoral artery and a radial artery.

62. (Previously Presented) The system of claim 61, wherein the second externally accessible channel is a jugular vein.

63. (Previously Presented) The system of claim 48, wherein the first externally accessible channel is selected from one of a femoral artery and a radial artery.

64. (Previously Presented) The system of claim 63, wherein the second externally accessible channel is a jugular vein.